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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,695	09/02/2003	Kyong-Min Shin	U 014789-4	3486

140 7590 04/04/2005

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

PRONE, CHRISTOPHER D

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/653,695

Applicant(s)

SHIN ET AL.

Examiner

Christopher D Prone

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-3, drawn to a method of producing a flexible self-expandable stent, classified in class 87, subclass 33.
- II. Claims 4-5, drawn to a flexible self-expanding stent, classified in class 623, subclass 1.13.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process wherein first the rubber tube is inserted into the outer stent, subsequently the ends are sewn together and then the inner stent is inserted into the rubber tube subsequently those ends are then sewn together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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During a telephone conversation with William Evans on 3/21/05 a provisional election was made with traverse to prosecute the invention a flexible self-expanding stent, claims 4 and 5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-3 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it exceeds the 150-word limit. Correction is required. See MPEP § 608.01(b).

Drawings

The replacement-drawing sheet (Figures 5A-D) was received on 4/23/04. These drawings are acceptable.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) are not mentioned in the description: “*ℓ*” and “*2ℓ*”. The specification refers to these lengths as elements “P” and “2P.” Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103 as being unpatentable over United States Patent 5,667,523 Bynon in view of United States Patent 5,718,159 Thompson.

Bynon discloses the invention substantially as claimed being a self expandable stent assembly comprising inside and outside stent bodies with a tubular graft member closely fit between said bodies, all having similar lengths with their ends being integrated into a single structure shown in figures 1-18 of Bynon.

However, Bynon does not disclose the zigzag stent structure, the use of memory metal wires, or that the inner tubular member comprises rubber.

Thompson teaches the use of a stent with a zigzag structure comprising 2 wires made of memory metal, wherein a first wire has twice the longitudinal length of a second wire, covered in a tubular member comprising textile sheets made of a rubber polyurethane in the same field of endeavor for the purpose of providing a more flexible vascular stent with reduced permeability shown in figures 15-17 of Thompson and described in column 4 on lines 7-17.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the stent structure and materials of Thompson in the assembly of Bynon in order to create a dual supported stent

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graft with shape memory characteristics able to prevent leakage of undesired fluids, yet readily accommodating radial expansion and contraction.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bynon and Thompson as applied to claim 4 above, and further in view of United States Patent 5,522,881 Lentz

The combination of Bynon and Thompson as described above discloses the invention substantially as claimed being a dual stent structure with its ends immersed in a polyurethane solution, described in column 13 on lines 23-29. However, the combination does not disclose that the ends of the inside and outside stents are stitched to the rubber tubular member.

Lentz teaches the use of an implantable tubular member in the same field of endeavor comprising a tubular conduit member that encompasses an outer stent body for the purpose of securely anchoring the stent to the conduit and preventing the stent from unwinding and or puncturing a body vessel.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the sutures of Lentz in combination with the dual stent structure of Bynon and Thompson, described above, in order to prevent the stent ends from unwinding and or puncturing a body vessel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D Prone whose telephone

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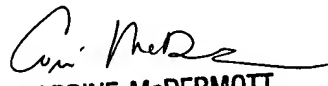
number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-6085. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDP

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